K082077
7 of 6

SEP - 2 2008

5 510(K) SUMMARY

General Information

5.1 Applicant

Date: June 13, 2008

Name: Corscience GmbH & Co. KG

Address: Henkestr. 91
D-91052 Erlangen
Germany

Contact person in the U.S.: **Patrik R. Karem**
Address SOMNO TECH, L.L.C.
700-706 Seco Rd.
Monroeville, PA 15146
Telephone: 412 – 372 – 8571
FAX: 412 – 372 – 8575
E-Mail: rpkarem@somnotech.com

Contact person in Germany: **Christine Baumann**
Telephone: 01149 9131 977986 – 25
FAX: 01149 9131 977986 – 59
E-Mail: baumann@corscience.de

Signature: C. Baumann

5.2 Trade Name

BT3/6, BT12

5.3 Common Name or Classification Name

Wireless electrocardiograph

5.4 Establishment Registration Number

3005488716

5.5 Facility Address

Corscience GmbH & Co. KG
Henkestr. 91
D-91052 Erlangen
Germany

5.6 Device Classification

5.6.1 Classification

This is a class II device

5.6.2 Classification panel

Panel: cardiovascular
Product Code DXH

5.6.3 Regulation Number

870.2920

5.7 Reason for Premarket Notification

Approval of new ECG device.

5.8 Predicate Device Description

5.8.1 Name

CG-7000DX-BT

5.8.2 Predicate Device Company

Card Guard Scientific Survival, LTD.

5.8.3 Predicate Device 510(k)#

K052556

5.9 Device Description

BT3/6, BT12 is a compact ECG device which is worn on the body and is capable of wireless data transmission. With the BT3/6 type, 2 ECG leads (II – III according to Einthoven) can be measured via a 4-pin cable. The receiving unit can calculate four additional leads (lead I according to Einthoven, aVL, aVR, aVF according to Goldberger).Type BT12 has a 10-pin cable, which, in addition to the leads of the BT3/6 variant, can also measure the 6 leads according to Wilson. With this cable, one can select among 3-, 6- or 12-channel ECG measurements. The cables of the BT are pluggable and therefore can be easily changed.

The electrode clips on the patient cables are suitable for connection to button and tab electrodes. It has an integrated electrode contact detector and a heart rate meter, the results of which are displayed on an integrated LCD display. Thanks to the integrated radio data transmission technology, BT3/6, BT12 is able to transmit ECG data online over a range of up to 10 m to a monitor or recording unit for further evaluation.

BT3/6, BT12 can be used in all medical applications where the long, stiff trunk cables are a problem due to their weight, their motion artifacts or their electromagnetic susceptibility or because they limit the patient in his freedom of motion. Especially significant are the applications in which it is necessary for the patient to move around freely, for example when the patient is undergoing a stress electrocardiogram.

BT3/6, BT12 is compact and simple to operate. A clip allows the device to be fixed to the patient's clothing. BT3/6, BT12 is powered by two standard AA cells.

Patient contacting components are the electrodes. BT3/6, BT12 is intended for use with approved, biocompatible electrodes only.

A user manual with detailed description of the device is submitted in section 13 "Proposed Labeling".

5.10 Intended Use Statement

The BT3/6 (3/6-lead) and BT12 (12-lead), hereafter referred to as the "BT devices", are battery powered devices capable of acquiring and transmitting a standard electrocardiogram (EKG) to be applied by medically trained persons for the purpose of cardiac monitoring and diagnosis performed by medical professionals. The collected data is not interpreted by the BT device as this is done by the monitoring device operated by medical professionals. The collected data is processed by the BT device and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device for display, review, printing, saving and post event processing by medical professionals. Use of the BT devices is not restricted to adult population, but is also intended for infants weighing less than 10 kg (22 lbs.).

Measurements taken by the BT devices are only significant if considered in connection with other clinical findings. No therapy or drugs can be administered based solely on ECG data derived from the BT devices. BT devices are not intended for monitoring critical patients and are not intended for intracardial use.

5.11 Required Components

- BT3/6, BT12
- User manual
- Batteries
- Cable 4-lead (BT3/6 only)
- Cable 10-lead (BT12 only)

Parameter	BT3/6, BT12	Predicate Device CG-7000DX-BT 12 Lead ECG Recorder/ Transmitter
Intended Use	The BT3/6 (3/6-lead) and BT12 (12-lead), hereafter referred to as the "BT devices", are battery powered devices capable of acquiring and transmitting a standard electrocardiogram (EKG) to be applied by medically trained persons for the purpose of cardiac monitoring and diagnosis performed by medical professionals. The collected data is not interpreted by the BT device as this is done by the monitoring device operated by medical professionals. The collected data is processed by the BT device and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device for display, review, printing, saving and post event processing by medical professionals. Use of the BT devices is not restricted to adult population, but is also intended for infants weighing less than 10 kg (22 lbs.). Measurements taken by the BT devices are only significant if considered in connection with other clinical findings. No therapy or drugs can be administered based solely on ECG data derived from the BT devices. BT devices are not intended for monitoring critical patients and are not intended for intracardial use.	12-Lead ambulatory electrocardiograph capable of recording and transmitting up to 40 standard ECGs for the purpose of cardiac monitoring and diagnosis, incorporates recording/ transmitting circuitry, graphic LCD, a package of firmware tools and is intended for use by a medical professional: a. The ECG is recorded and transmitted to a remote receiving station for consultation with a cardiologist. b. The ECG is recorded and transferred to a remote hand held device/PC/printer for viewing and processing.
ECG interpretation software	No interpretation	No interpretation
Input dynamic range	+/- 5 mV	+/- 5mV
Frequency response bandwidth	0,05-150Hz / according to EC11 and IEC 60601-2-51	
Resolution	24 bit A/D converter (15 bit transmitted) 2,58 µV/bit	10 bit
Leads	3/6 or 12	12
CMRR	>94 dB	60 dB

Parameter	BT3/6, BT12	Predicate Device CG-7000DX-BT 12 Lead ECG Recorder/ Transmitter
Pacemaker detection	Yes	Yes
Current consumption	For BT12: Operation (incl. transmission): 148 mA stand-by: 37 mA	Record: 55 mA Transmit: 75 mA
Battery type	2 x 1,5V alkaline or 2 x 1,2V rechargeable	9V alkaline
Input impedance	20 MΩ	> 10 MΩ
DC offset correction	± 190 mV	± 75 mV
ECG storage capacity	5 min/12 channel when transmission is interrupted	4-20 s length, 40-10 recordings (event recorder)
Temperature range	Operation: 0...50°C Storage : -20...70°C	Operation: 0...40°C Storage : -20...65°C
Display	LCD	LCD
Weight	260 g incl. batteries and cable 154 g without batteries, incl. cable	274 g incl. batteries 228 g (without batteries and cable)
Dimensions in mm	61 x 106 x 23	168 x 78 x 40
A to D sampling rate	500 samples/sec	500 samples/sec
data transmission	wireless	wireless
Degree of protection against penetration of water	IPX3	IPX0
Classification	BF	BF
Defibrillation protection	Device itself is not defibrillation proof, but ECG patient cable supplied with the device by manufacturer has defibrillation protection circuit. Note in manual that guarantee of defibrillation protection can be given only in combination with original cable.	The CG-7000DX-BT is not a defibrillation-proof device (optional cable available for defibrillation proof use).

Both devices are intended for continuous wireless transmission of ECG signals and both are portable due to battery-supply and light weight. Both devices are capable of acquiring the ECGs at remote sites and transmitting them via radio transmission to an appropriate receiving station. Therefore, the device under consideration and the predicate device are very similar in their basic functions. The predicate device claims conformance with the ECG standards ANSI/AAMI EC11:1991, and ANSI/AAMI EC38:1998. BT3/6, BT12 is conform with hardware requirements of EC11 and EC38. Exception is the offset-voltage requirement of ±300mV. With BT3/6, BT12 an offset of up to ±190mV does not influence the baseline of the ECG signal. But performance is better than that of the predicate device which states DC offset of only ±75 mV.
The differences in technological characteristics between BT3/6, BT12 and the predicate device can be summarized as follows:

The resolution of the BT devices is higher than that of the predicate (15 bit compared to 10 bit) which results in a better ECG signal quality.

The predicate device is available only for the acquisition of 12-lead ECGs, whereas the device under consideration is available for measuring either a 12- or a 3/6-lead ECG (BT12 and BT3/6).

CMRR of the BT devices is higher than with the predicate (>94 db compared to 60 db). This results in a better ECG signal quality in the presence of interference signals.

Input impedance is specified higher with the BT devices (20 MΩ compared to >10 MΩ). Therefore, ECG signal quality is less dependent on electrode contact quality with the BT as with the predicate.

The two devices differ in their data storage functionality. The BT stores data only when the wireless radio connection is interrupted, e.g. when the patient leaves the transmission range. After the connection is re-established the stored data is transmitted to the receiving unit. Interruption of the transmission is indicated on the device. The BT devices are not intended for use as Holter monitors. The CG-7000DX-BT has a limited event storage capability of up to 40 ECG recordings.

The BT devices and the predicate are capable of continuously transmitting ECG data.

The graphic display of the CG-7000DX-BT is able to display the measured ECG, while the BT devices can display the ECG on the receiving unit only. But, the LCD of the predicate is of low resolution and should not be used to make a diagnosis.

The BT devices have a higher degree of protection against penetration of water (IPX3).

5.13 Summary of Device Testing

The BT3/6, BT12 has been tested according to IEC 60601-1 and IEC 60601-1-2 by accredited laboratories and has shown full compliance to these standards and the other standards listed in chapter 9 of this 510(k).

BT3/6, BT12 fulfils only those parts of the standards ANSI/AAMI EC11:1991, and ANSI/AAMI EC38:1998 that relate to hardware requirements. In case the device is used in combination with appropriate software and the user manual is adapted to the standards, it is possible to completely comply with these standards. Since the BT3/6, BT12 is supplied without diagnostic/interpreting software, the manufacturer cannot claim full compliance to ANSI/AAMI EC11:1991, and EC38:1998.

The software was tested as described in section 16 "Software". The corresponding FDA software guidelines were followed.

5.14 Conclusions

Based on the above, Corscience GmbH & Co. KG concludes, that BT3/6, BT12 is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

TUV SUD America
c/o Mr. Olaf Teichert
Third Party Reviewer
1775 Old Highway 8, NW Ste. 104
New Brighton, MN 55112-1891

Re: K082077
Trade/Device Name: BR3/6, BR12
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: August 13, 2008
Received: August 18, 2008

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082077

Indications for Use

510(k) Number (if known): 082077

Device Name: BT3/6 BT12

Indications for Use:

The BT3/6 (3/6-lead) and BT12 (12-lead), hereafter referred to as the "BT devices", are battery powered devices capable of acquiring and transmitting a standard electrocardiogram (EKG) to be applied by medically trained persons for the purpose of cardiac monitoring and diagnosis performed by medical professionals. The collected data is processed by the BT device and then transmitted via a standard wireless link to a monitoring device, such as a PC or hand-held device for display, review, printing, saving and post event processing by medical professionals. The collected data is not interpreted by the BT device as this is done by the monitoring device operated by medical professionals. Use of the BT devices is not restricted to adult population, but is also intended for infants weighing less than 10 kg (22 lbs.).

Measurements taken by the BT devices are only significant if considered in connection with other clinical findings. No therapy or drugs can be administered based solely on ECG data derived from the BT devices. The BT devices are not intended for monitoring critical patients and are not intended for intracardial use.

Federal law restricts this device to sale by or on the order of a physician.

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082077